

Three-Year Outcomes of Spinal Cord Stimulation across Multiple Indications: A Prospective, Global, Real-world Registry

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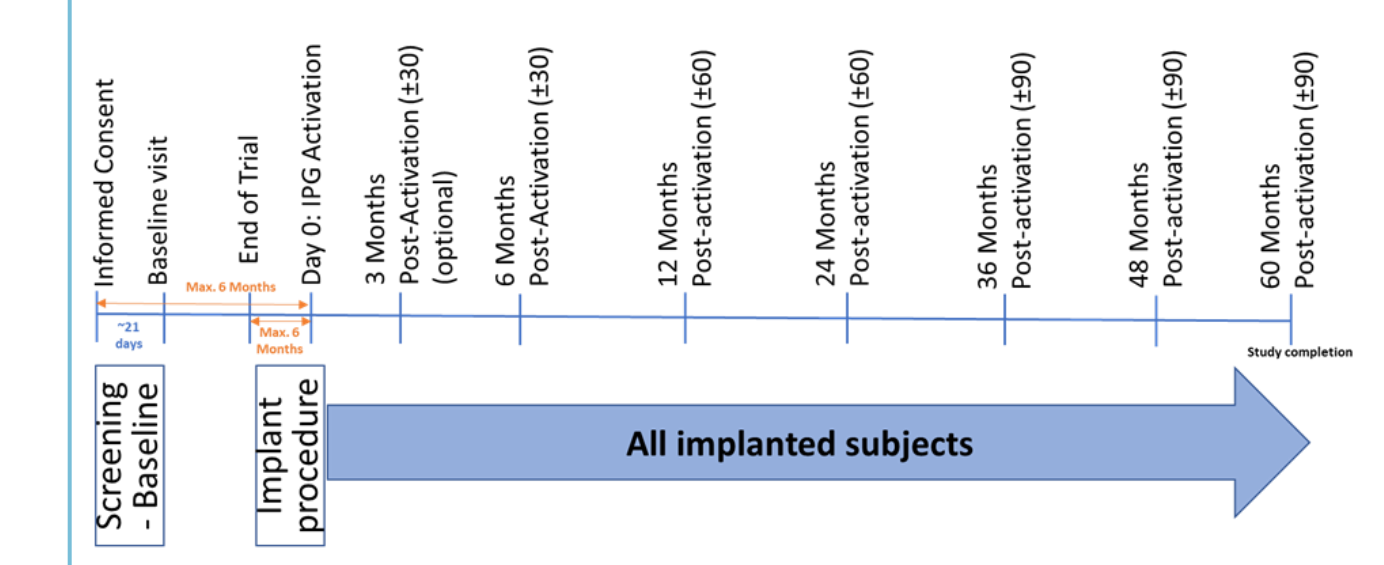
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BACKGROUND

Spinal cord stimulation (SCS) has been used for decades to treat chronic neuropathic pain with technological and clinical advancements supporting its safety and effectiveness across multiple pain etiologies.¹⁻⁷ In contrast, conservative medical management for chronic low back pain has been associated with modest average pain reductions, typically ranging from 4-14%, which often fall below commonly accepted thresholds for clinically meaningful improvement used in SCS studies including $\geq 50\%$ pain relief, functional improvement, and patient reported global benefit.⁸ While randomized control trials have established the efficacy of SCS under controlled conditions, their limited duration and restrictive inclusion criteria may not fully reflect long-term, real-world outcomes across heterogeneous patient populations. To address this gap, a large, multi-center, global trial was conducted to evaluate the durability and clinical effectiveness of SCS across approved indications using meaningful patient-centered outcomes over extended follow-up.

METHODS

Study design and Schematic	
Study Design	Prospective, multicenter, single-arm study (NCT01719055)
Study Device	Boston Scientific SCS Systems
Primary Endpoint	Proportion of subjects with $\geq 50\%$ reduction from Baseline Visit in average targeted pain intensity
Secondary endpoints	Secondary endpoints*: Pain intensity (VNRS), disability (ODI), health-related quality of life (EQ5D-5L) and patient satisfaction (PGIC)

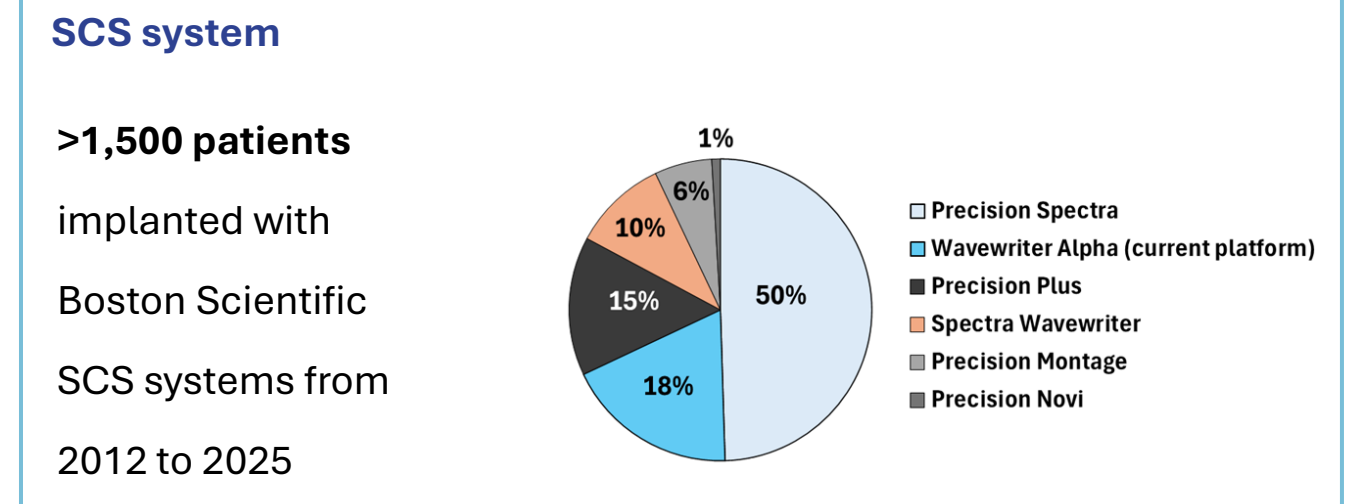
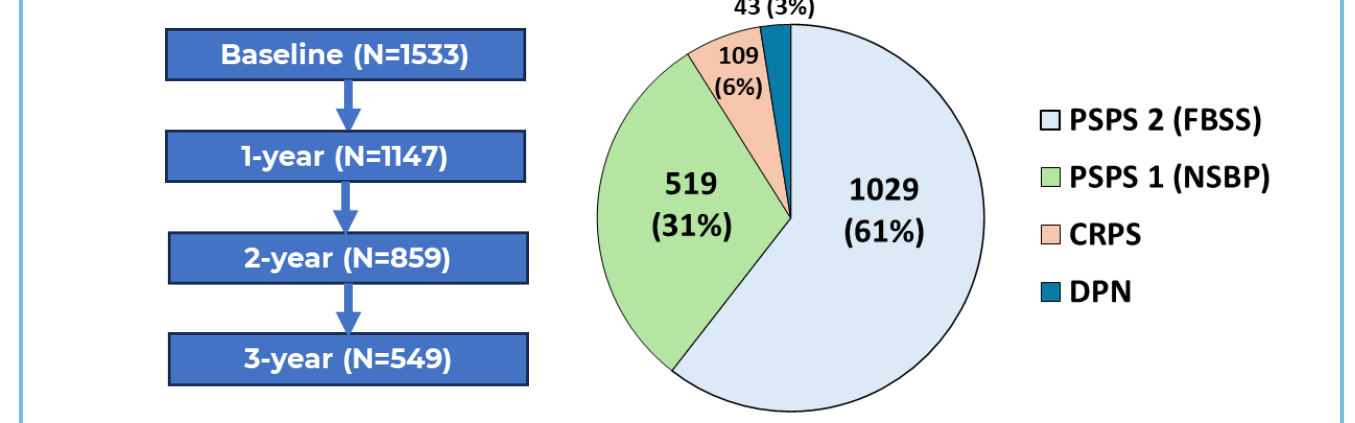


* VNRS: Verbal Numerical Rating Scale; ODI: Oswestry Disability Index;; EQ5D-5L EuroQol 5 Dimension 5 Level; PGIC: Patient Global Impression of Change

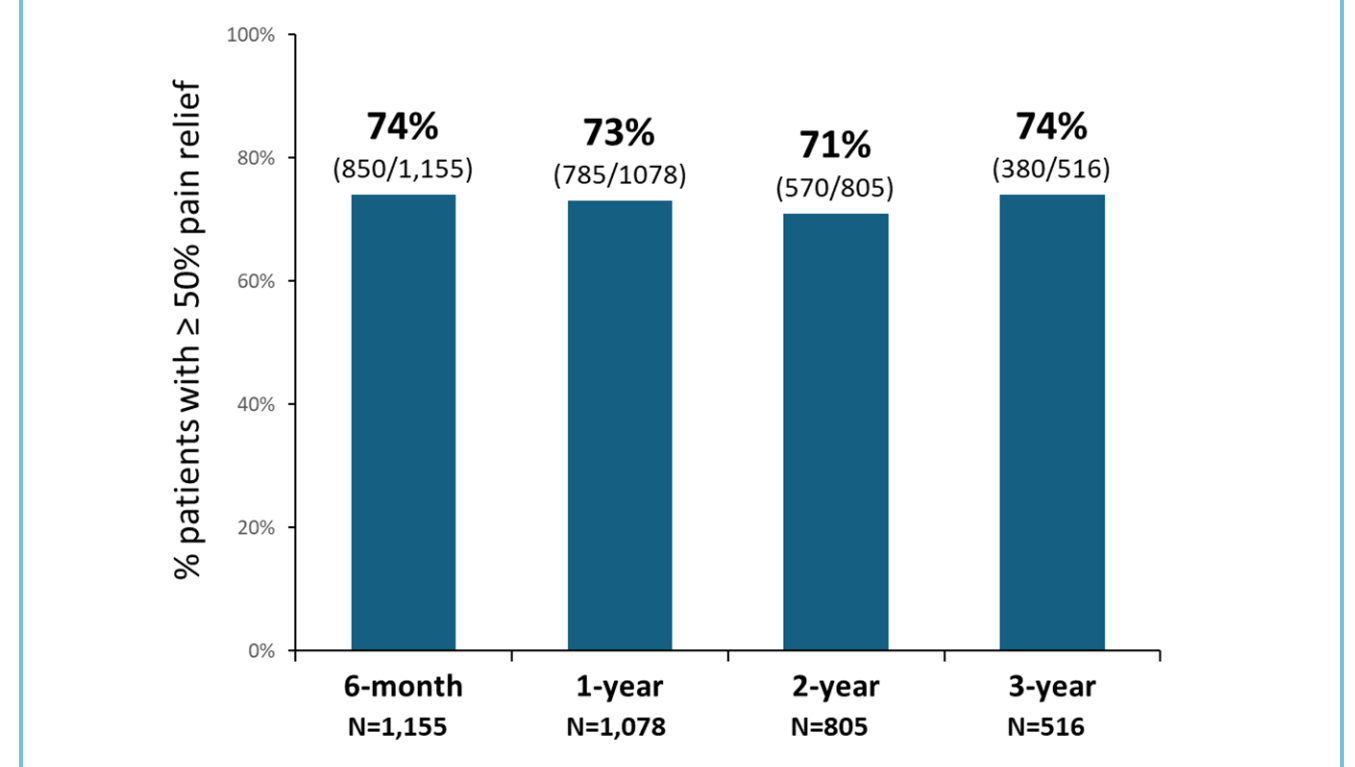
RESULTS

Baseline characteristics and patient disposition					
Demographic data	All patients	PSPS type 2 (FBSS)	PSPS type 1 (NSBP)	CRPS	DPN
Implanted subjects (N)	1,533	1,029	519	109	43
Age (years)	58 years	58 years	59 years	50 years	63 years
Gender (% female)	57%	55%	60%	65%	38%
Pain duration (median)	8 years	9 years	7 years	5 years	10 years

PSPS: Persistent Spinal Pain Syndrome
 Type 1: NSBP (Non Surgical Back Pain)
 Type 2: FBSS (Failed Back Surgery Syndrome)
 CRPS: Complex Regional Pain Syndrome
 DPN: Diabetic Peripheral Neuropathy

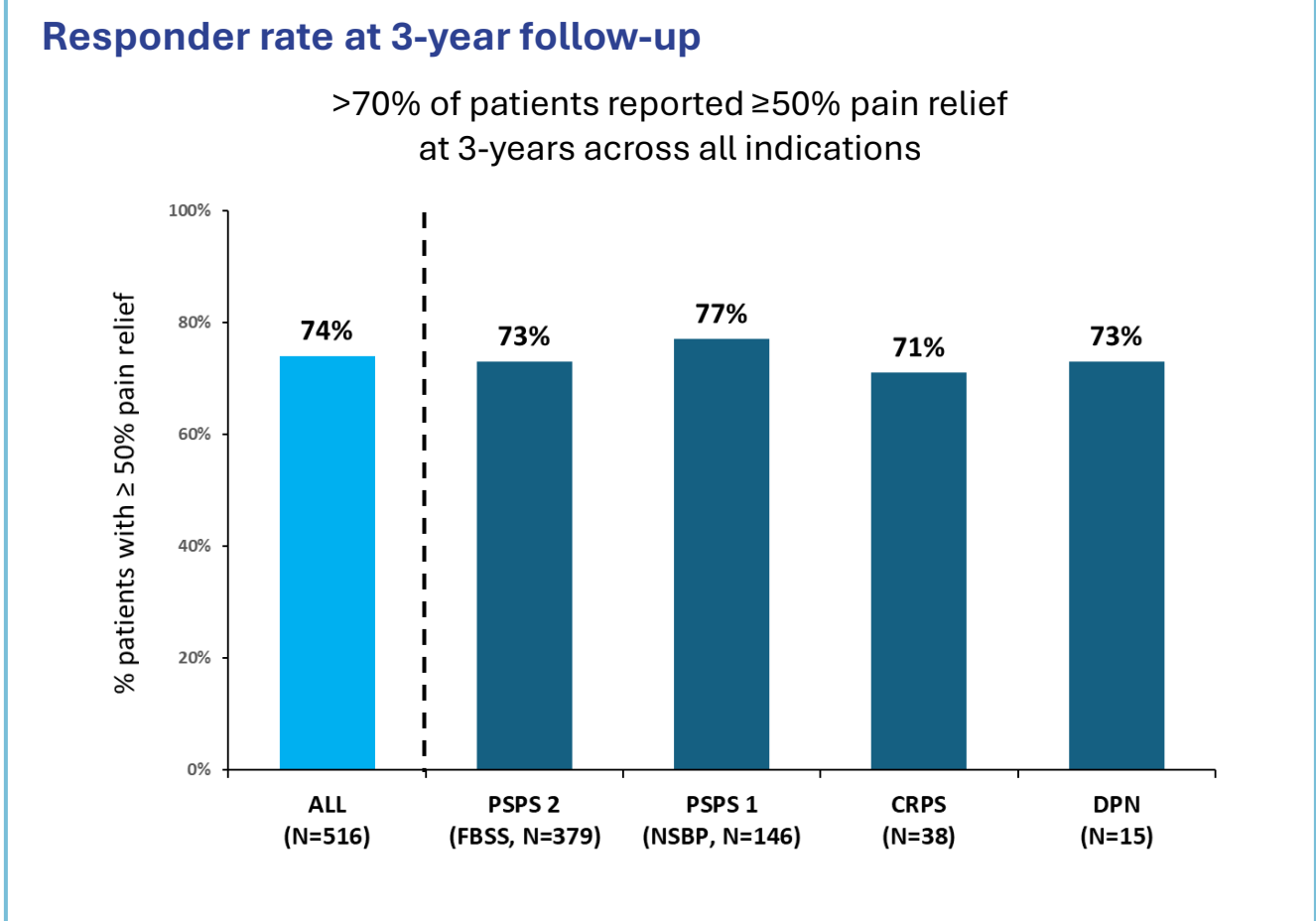


RESPONDER RATE OUT TO 3 YEARS

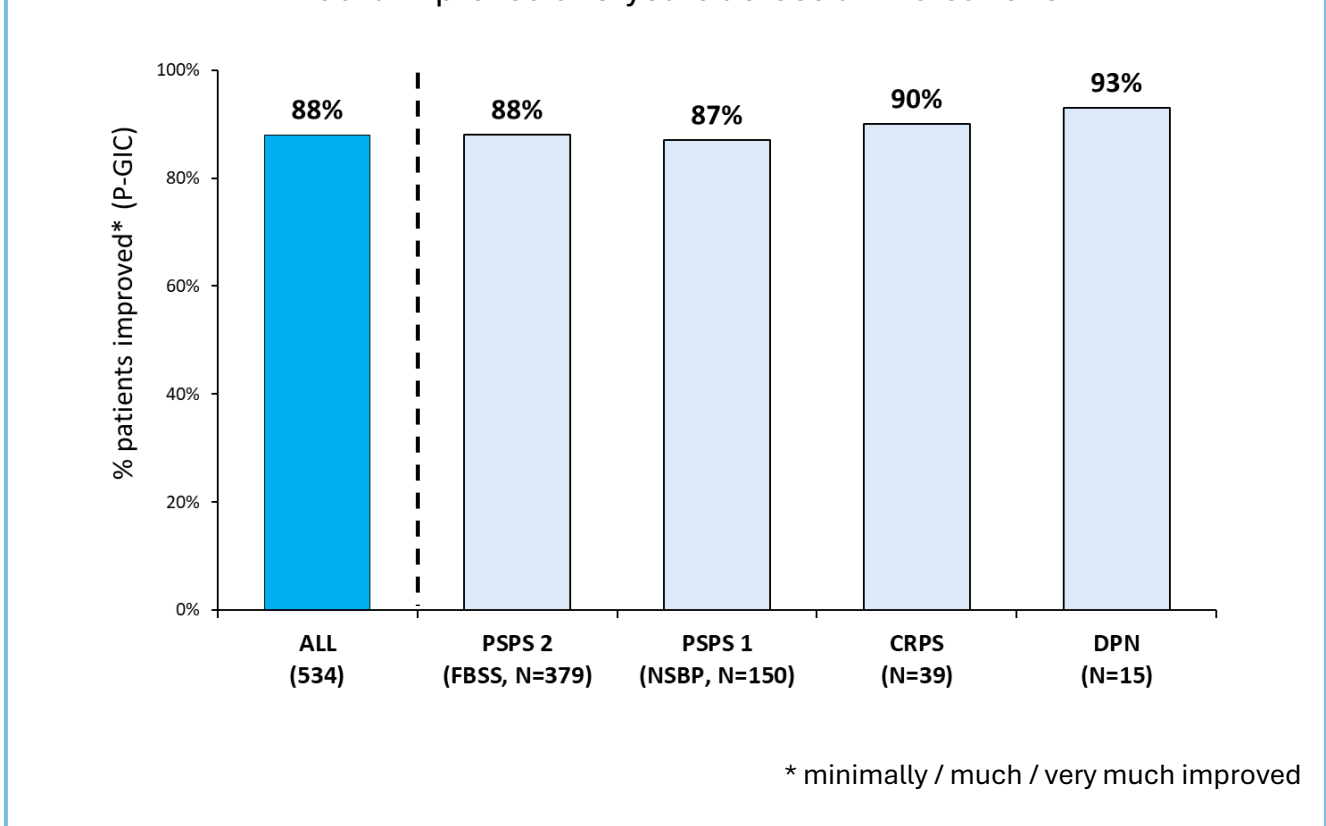


>70% of all patients who completed their study visits out to 3 years reported $\geq 50\%$ pain relief

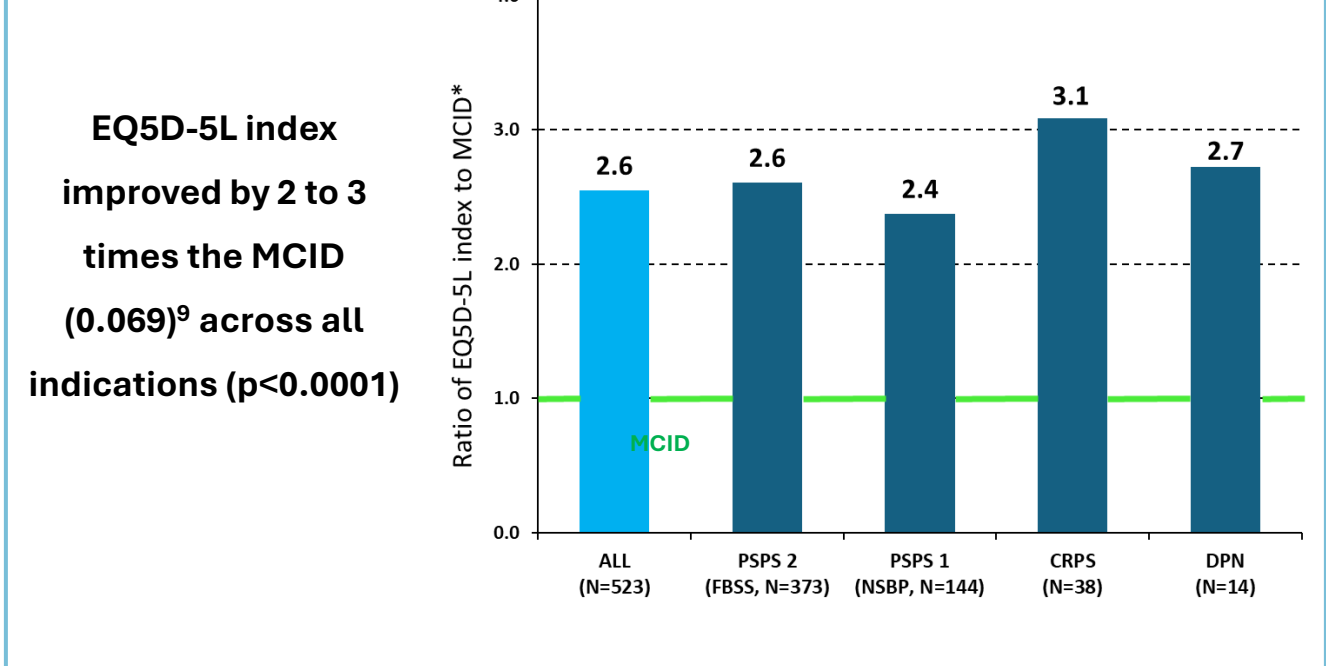
THREE-YEAR OUTCOMES BY INDICATION



Patient satisfaction at 3-year follow-up



Quality of life at 3-year follow-up



CONCLUSION

This global real-world prospective registry demonstrates the efficacy and durability of SCS therapy across multiple indications.

Three-year results across various indications showed:

- **>70% responder rate**
- **$\sim 90\%$ patients reported being improved**
- **Significant improvement in quality of life**

This effectiveness report complements safety findings which had showed low annualized explant rate (all cause: 3.5%; loss of efficacy: 1.1%).⁶ The present analysis focused on 3-year outcomes. Extended follow-up is ongoing.

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- Edward Goldberg is employee of Boston Scientific.



INDICATIONS FOR USE



View Boston Scientific Spinal Cord Stimulator System Indications, Safety, and Warnings at [bostonscientific.com/scs-indications](https://www.bostonscientific.com/scs-indications)

OUS Indications for Use - CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months. Full stimulation parameter ranges and options for both paresthesia-based and subperception therapy are available for clinician's use throughout the patient's experience and treatment with SCS.

Warning: Stimulation modes. Only paresthesia-based stimulation mode has been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population

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